

REMARKS

Claims 1 and 17 have been amended to more particularly point out and distinctly define the claimed invention. The claim language has been amended to remove phrases left over from the translation from the original German. No new matter has been added.

In paragraphs 2-19 of the Office Action the Examiner rejected Claims 1-16 under 35 U.S.C. §103(a) as being obvious over CAB8-Computer Applications in Biotechnology, June 25-27, 2001 (hereinafter "Cornelissen") in view of Biotechnology and Bioengineering, vol. 34, pp 592-599 (1989) (hereinafter Majors), and U.S. Published Application No. 2002/0138454 A1 (hereinafter Gruenberg), and further in view of United States Patent No. 6,402,941 (hereinafter Lucido).

Reconsideration is requested.

Claim 1 recites a novel method for biotechnologically producing valuable products using a system of feed receptacles, a bioreactor, pumps, a cross flow filtration unit and at least two harvest receptacles, one for storing filtered permeate and a second for storing concentrated retentate. Claim 1 further recites that the method measures the cell concentration of the bioreactor by use of the control unit (6), an analytical system (27), a sensor (28), an analyzer (41), a regulator (42), and a reference operator (43), and then adjusts the cell concentration to a predetermined level by a moving cells from the bioreactor (1) to the second harvest receptacle (18) through the use of a harvest pump (20).

The Examiner has stated in paragraph 6 of the Office Action that the primary reference, Cornelissen does not teach a second harvest vessel. The Examiner has also stated in paragraph 8 of the Office Action that Cornelissen does not disclose a method for measuring the cell concentration in the bioreactor. Applicants submit that the Examiner is correct in highlighting these deficiencies in the primary reference and further submit that neither Cornelissen, nor the secondary references, disclose or suggest the recited method, including each and every element used to measure the cell concentration and then readjust the cell concentration in the bioreactor to the desired level.

To alleviate the deficiencies in Cornelissen, the Examiner has cited three additional documents that contain unrelated teachings to the present invention, but do

provide systems for moving medium through a bioreactor. The first reference is Major, which discloses a continuous fermenter for producing lactate. The only disclosure in the journal article cited by the Examiner is a simple figure on page 593, and one paragraph on page 594, which briefly describes the re-circulation process used in Major. The description in Major of a recycling system does not render obvious the system disclosed in the Claim 1 of the present invention because there is no instruction or need described in Major to use a more complicated cell growing system as taught in the present invention, nor is there an instruction in Cornelissen to use a recycling system as taught in Major. Moreover, neither references discloses or suggests the need to measure cell concentration, a system for cell concentration measurement or a system for readjusting cell concentration as recited in the present claims.

Next the Examiner points to Gruenberg and Lucido in an attempt to alleviate the deficiency in Cornelissen and Major, namely the lack of instruction regarding the method for measuring cell concentration and the method for achieving the desired cell concentration in the bioreactor. As disclosed above, Claim 1 recites that the method measures the cell concentration of the bioreactor by use of the control unit (6), an analytical system (27), a sensor (28), an analyzer (41), a regulator (42), and a reference operator (43), wherein the cell concentration is removed from the bioreactor (1) to the second harvest receptacle (18) through the use of a harvest pump (20). None of these claim elements are disclosed in the cited prior art in the combination recited in Claim 1. Therefore each and every element of Claim 1 is not disclosed or suggested by the cited prior art.

Specifically with regard to Gruenberg, there is only a teaching with regard to measuring the feed stream of the nutrient mixture into the bioreactor, not a method of measuring the cell concentration in the bioreactor and then regulating the cell concentration of the bioreactor. *See* Gruenberg at paragraphs 0019, 0064, 0109, 0121-0122. Additionally, Claim 1 recites the following elements: a control unit (6), an analytical system (27), a sensor (28), an analyzer (41), a regulator (42), and a reference operator (43). The only elements recited in Gruenberg related to measurement of nutrient in the bioreactor (not cell concentration) are a peristaltic pump, a Software solution as part of the Bioprocess Automation system and a Mettler balance. These elements are not equivalent to the control unit (6), an analytical system (27), a sensor (28), an analyzer

(41), a regulator (42), and a reference operator (43) of the Claim 1. Further, since the elements disclosed in Gruenberg, relate to a method for measuring nutrient feed, it further has no relation to the measuring and removing of cell concentration.

Lucido discloses an apparatus for biological treatment of environmental contaminants and waste. The teachings highlighted by the Examiner in Lucido are contained in col. 8, lines 30-35, which teach that an optical sensor can be used to measure turbidity in the bioreactors, and that a higher turbidity can indicate a higher viable cell concentration. *See id.* Applicants submit that the above teaching does not render obvious the recited claim elements in Claim 1, namely, a control unit (6), an analytical system (27), a sensor (28), an analyzer (41), a regulator (42), and a reference operator (43), wherein the cell concentration is removed from the bioreactor (1) to the second harvest receptacle (18) through the use of a harvest pump (20). There is not even a process disclosed in Lucido to alter the cell concentration in the bioreactor, only a process that recites an “alarm is hooked up to a computer via telephone lines which relays the sounding of the alarm to a central station. At this station the problem can be assessed and a repair unit dispatched as needed”. *See* Lucido at Col. 8, lines 36-40. This process is not comparable to the fully automated system recited in Claim 1 of the present invention. Furthermore, because Lucido is related to a process for removing industrial waste from sewage systems, Applicants submit that this is non-analogous art, and therefore would not be used by a person skilled in the art looking to add to the teachings of Majors and Cornelissen.

The remaining dependent Claims 2-16 all incorporate each and every limitation of Claim 1, and therefore are also not rendered obvious by the cited prior art.

Therefore because the cited prior art does not teach or suggest each and every element of Claims 1-16, it is requested that the above §103(a) rejection be withdrawn.

In paragraphs 20-24 of the Office Action the Examiner rejected Claims 17-19 and 21 under 35 U.S.C. §103(a) as being obvious over Cornelissen in view of Major and Gruenberg.

Reconsideration is requested.

The device of Claim 17 contains all of the elements discussed above in detail with regard to the method Claim 1. Additionally as discussed, the cited prior art, namely, Cornelissen, Major and Gruenberg (and even Lucido, which has not been included in this

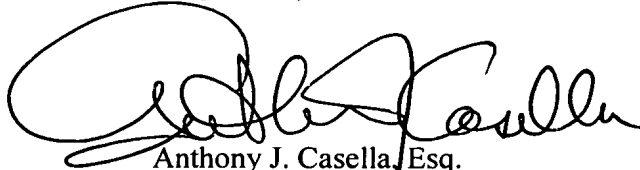
rejection), does not teach or suggest each and every element of Claim 17 of the present application. Specifically, the cited prior art does not teach the elements for measuring cell concentration in a bioreactor and the elements necessary for removing excess cell concentration from said bioreactor as recited in Claim 17.

Therefore, it is requested that the §103(a) rejection with regard to Claims 17-19 and 21 be withdrawn.

Based upon the above amendments and remarks, Applicants respectfully submit that Claims 1-19 and 21 are allowable over the prior art and that the present application is in proper form for allowance.

Favorable consideration and early allowance is respectfully requested and earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Anthony J. Casella', is written over the typed name and contact information.

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